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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,763	11/15/2000	Ib Mendel-Hartvig	10806-105	3460

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DINSMORE & SHOHL, LLP
1900 CHEMED CENTER
255 EAST FIFTH STREET
CINCINNATI, OH 45202

EXAMINER

CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/24/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,763

Applicant(s)

Mendel-Hartvig et al

Examiner

Chris Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 15, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above, claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I - claims 1-21 and 25-28 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the method of Group II employs the device of Group I and thus would not be unduly burdensome for the Examiner to examine all of the claims. This is not found persuasive because the search for the method of Group II involves the use of additional search terms on commercial data bases that are not required for the device of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 U.S.C. § 112

2. Claims 1-21 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague. The last 4 lines of the claim are vague because the recitations of "adapted to" is not clear as to how the separation means is modified to prevent contact of the flow matrix with the liquid containers.

Claim 25 is vague and indefinite as to what constitutes "at least one other assay component".

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Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8, 10, 12, 13, 19, 20, 21, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramel et al.

Ramel et al (U.S. Patent 5,260,221) disclose methods and apparatus for the measurement of an analyte employing a continuous flow path, which has a sample receiving region as an internal region, which is brought into contact with the adjacent two regions to serve as a bridge. Prior to the addition of sample to the sample receiving region, the sample receiving region is inhibited from transport of fluid to complete the path. After receiving sample, the sample receiving region acts as a bridge between first and second portions of the path, where the first portion serves to transport fluid to the sample receiving region and the second portion is the measuring region (col. 2, line 63, to col. 3, line 48). The measuring element will be an extended member which allows for flow of the reagent solution through the measuring element. The measuring element will have one or more members of the signal producing system present on the measuring element, where the height or distance of the signal board, the distance from the sample receiving element to the signal front, will be related to the amount of analyte in the sample and

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on the sample receiving member. Alternately, appearance of a signal at a predetermined area can indicate the presence or absence of an analyte. By appropriate choice of members of the signal producing system for a quantitative assay, visually observable color fronts may be obtained, fluorescent signals, or the like (col. 3, line 49, to col. 4, line 18). The means for inhibiting fluid flow is a slide which can be moved from a first position, where the sample receiving element receives the sample, to a second position where the sample receiving element serves as a bridge between the two other elements of the flow path. The slide prevents sample from spreading to the other elements of the flow path before it is time to carry out the assay. The slide is also responsible for releasing a reagent solution that contacts the sample receiving region for development of the assay (col. 4, lines 19-62). Different protocols may be used for different analytes. The measuring region can contain anti-analyte antibodies. A wicking solution containing enzyme labeled analyte is employed for detection of the analyte (col. 6, lines 64-68). Assays such as ELISA assays and sandwich assays can be performed in the disclosed device (col. 4, line 63, to col. 5, line 2).

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramel et al in view of Foster et al.

See above for the teachings of Ramel et al.

Ramel et al differs from the instant invention in failing to teach a kit arrangement containing the disclosed device and reagents for carrying out assays in the device.

Foster et al (U.S. Patent 4,444,879) discloses a kit containing apparatus, reagents, and instructions for carrying out immunoassays (see Fig. 6).

It would have been obvious to one of ordinary skill in the art to place the device of Ramel et al in a kit arrangement with the necessary reagents for carrying out assays, as taught by Foster et al, because kits provide the well known advantage of convenience and economy.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
November 22, 2003


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641